

To:

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

FOR FURTHER ACTION  
See paragraph 2 below

International application No.  
PCT/GB2004/005348

International filing date (day/month/year)  
21.12.2004

Priority date (day/month/year)  
22.12.2003

International Patent Classification (IPC) or both national classification and IPC  
C12Q1/04. G01N33/52

Applicant  
PRAIL PRICE RICHARDSON DIAGNOSTICS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

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1. Statement

Novelty (N)	Yes: Claims	1-14
	No: Claims	
Inventive step (IS)	Yes: Claims	1-14
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

**Re Item V.**

- 1 Reference is made to the following document:

D1: EP-A-0 841 403 (IDEMITSU KOSAN COMPANY LIMITED) 13 May 1998.

2. Claims 1-14 are novel (article 33(2)PCT).

The cited prior art does not disclose:

a device for characterising microorganisms, comprising a porous body having regions of different pore sizes associated with different chromogens specific for the enzymes produced by the microorganisms to be detected (claims 1-13);  
a method for characterising bacteria which makes use of the device of claims 1-13.

3. Independent claim 1 is inventive (article 33(3) PCT).

- a. D1 (see in particular page 4, lines 51-55 and claim 25), representing the closest prior art, discloses a device for detecting bacteria, comprising a first filter having a pore size of 30-70  $\mu\text{m}$  to separate bacteria from animal and vegetal cells, a second filter having a pore size of 0,45-4  $\mu\text{m}$  for trapping bacteria, and a dye for colouring bacteria.
- b. The main difference between claim 1 and D1 is that, in claim 1, the regions of different pore sizes are associated with different chromogens specific for the enzymes produced by the microorganisms to be detected. The technical effect produced by this difference is that the specificity of detection is enhanced, as different microorganisms are differentiated not only on the basis of the different enzymes they produce but also on the basis of their different sizes. The technical problem of claim 1 in view of the closest prior art is therefore to provide a device for characterising microorganisms with a better specificity. The solution proposed involves the use of regions of different pore sizes having different chromogens specific for the enzymes produced by the microorganisms to be detected. Such solution is inventive, as it is not suggested by the cited prior art.

- 3.1. Claims 2-13, dependent on inventive claim 1, are also inventive.

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AUTHORITY (SEPARATE SHEET)**

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- 3.2. The method of claim 14, which makes use of the inventive device of claims 1-13, is also inventive.
4. It is further noted that the term "IPTG" (claim 10) is unclear (article 6 PCT).